AMENDED IN SENATE AUGUST 23, 1996 AMENDED IN SENATE JUNE 24, 1996 AMENDED IN ASSEMBLY MAY 2, 1995

CALIFORNIA LEGISLATURE—1995-96 REGULAR SESSION

ASSEMBLY BILL

No. 1291

Introduced by Assembly Member Alpert

February 23, 1995

An act to amend Section 115080 of the Health and Safety Code, relating to radiation control.

LEGISLATIVE COUNSEL'S DIGEST

AB 1291, as amended, Alpert. Mammography equipment.

Existing law requires the State Department of Health Services to provide by rule or regulation for the general or specific licensing of persons to receive, possess, or transfer radioactive devices or equipment, and authorizes the department to require registration and inspection of other sources of ionizing radiation.

This bill would make certain findings and declarations relating to overlapping state and federal jurisdiction relating to mammographic X-ray equipment. It would declare the intent of the Legislature to reduce the duplication of requirements and costs.

Pursuant to existing law the registration fee and inspection frequency of radiation machines is based upon the priority classification of the machine pursuant to a prescribed schedule.

AB 1291 — 2 —

This bill would require the department to establish 2 different registration fees for mammography equipment, based upon whether the equipment is accredited by accrediting agency recognized independent under federal Mammography Quality Standards Act. The bill would preclude the fee for mammography equipment that is accredited by such an accrediting agency from exceeding the fee charged by the department for registration or accreditation of any high priority radiation machine.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. The Legislature finds and declares all of 2 the following:
- 3 (a) Both the State of California and the federal 4 government through the Food and Drug Administration 5 (FDA) have established extensive regulatory 6 requirements for any users of mammographic X-ray equipment.
- 8 (b) Those requirements include specific licensure of 9 equipment, technologists, physician supervision and 10 competency, quality assurance, film review, and 11 inspections.
- (c) There is a substantial duplication of requirements 12 13 compliance for facilities and costs utilizing 14 mammography equipment due the overlapping to jurisdiction and control of both the state and federal 15 government agencies. facilities 16 These must pay registration fees and accreditation costs for the same or substantially similar review process. 18
- 19 (d) It is the intent of the Legislature that registration 20 and license fees imposed by the state be reduced to 21 reflect the duplicative costs paid to the FDA and private 22 accrediting bodies to establish competency and 23 compliance.
- 24 (e) It is the intent of the Legislature that the 25 Department of Health Services evaluate current 26 requirements imposed by the department and the FDA

-3- AB 1291

1 and eliminate any inconsistencies that do not enhance 2 patient care and that impose an unreasonable regulatory 3 burden.

4 SEC. 2. Section 115080 of the Health and Safety Code 5 is amended to read:

115080. (a) The department shall provide by 6 a ranking of priority for inspection, regulation determined by the degree of potentially exposure of persons by ionizing radiation and the 10 requirements of Section 115085, and a schedule of fees, based upon that priority ranking, that shall be paid by persons possessing sources of ionizing radiation that are 12 13 subject to registration in accordance with subdivisions 14 (b) and (e) of Section 115060, and regulations adopted 15 pursuant thereto. The revenues derived from the fees 16 shall be used, together with other funds made available therefor, for the purpose of carrying out any inspections 17 18 of the sources of ionizing radiation required by this chapter or regulations adopted pursuant thereto. 20 fees shall, together with any other funds made available to the department, be sufficient to cover the costs of administering this chapter, and shall be set in amounts intended to cover the costs of administering this chapter for each priority source of ionizing radiation. Revenues generated by the fees shall not offset any general funds appropriated for the support of the radiologic programs authorized pursuant to this chapter, and the Radiologic Technology Act (Section 27), and Chapter (commencing with Section 114960). Persons who pay fees shall not be required to pay, directly or indirectly, for the share of the costs of administering this chapter of those persons for whom fees are waived. The department shall 32 take into consideration any contract payment from the 34 Health Care Financing Administration for performance of inspections for Medicare certification and shall reduce 35 36 this fee accordingly.

(b) A local agency participating in a negotiated agreement pursuant to Section 114990 shall be fully reimbursed for direct and indirect costs based upon activities governed by Section 115085. With respect to

3738

AB 1291 — 4 —

9

these agreements, any salaries, benefits, and other indirect costs shall not exceed comparable costs of the department. Any changes in the frequency of inspections or the level of reimbursement to local agencies made by this section or Section 115085 during the 1985–86 Regular Session shall not affect ongoing contracts.

- (c) The fees paid by persons possessing sources of ionizing radiation shall be adjusted annually pursuant to Section 100425.
- 10 (d) The department shall establish two different registration fees for mammography equipment pursuant to this section based upon whether the equipment is 12 accrediting 13 accredited by an independent agency 14 recognized under the federal Mammography Quality 15 Standards Act, (42 U.S.C. 263b). In no event shall the fee 16 established by the department for registration or 17 accreditation of mammography equipment that is 18 accredited by an independent accrediting agency 19 recognized under the federal Mammography Quality 20 Standards Act (42 U.S.C. 263b), exceed the fee charged 21 by the department for registration or accreditation of any high-priority radiation machine.